ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response
General Public—Adults	Patient Quarterly Assessment	134	3	45/60
General Public—Adults	CleverCap App Setup	134	1	10/60
General Public—Adults	Patient Interview Guide	10	1	90/60
Health Practitioners	Provider Screener	14	1	10/90
Health Practitioners	Provider Locator Form	7	1	10/90
Health Practitioners	Provider Pre-Training Assessment	7	1	30/60
Health Practitioners	Provider Post-Training Assessment	7	1	30/60
Health Practitioners	Provider Interview Guide	7	1	60/60
Health Practitioners	Clinic Assessment Baseline and Final	4	1	120/60
Health Practitioners	Clinic Assessment Every Six Months	4	2	90/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–24–0109]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Respiratory Protective Devices—42 CFR part 84'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on November 28, 2022 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Respiratory Protective Devices—42 CFR part 84 (OMB Control No. 0920–0109, Exp. 03/31/2024)—Revision—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The regulatory authority for the National Institute for Occupational Safety and Health (NIOSH) certification program for respiratory protective devices is found in the Mine Safety and Health Amendments Act of 1977 (30 U.S.C. 577a, 651 *et seq.,* and 657(g)) and the Occupational Safety and Health Act of 1970 (30 U.S.C. 3, 5, 7, 811, 842(h), 844). These regulations have, as their basis, the performance tests and criteria for approval of respirators used by millions of American construction workers, miners, painters, asbestos removal workers, fabric mill workers, and fire fighters.

Regulations of the Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC) also require the use of NIOSH Approved respirators. These regulations also establish methods for respirator manufacturers to submit respirators for testing under the regulation and have them certified as NIOSH Approved if they meet the criteria given in the above regulation. This data collection was formerly named Respiratory Protective Devices 30 CFR part 11 but in 1995, the respirator standard was moved to 42 CFR part 84.

NIOSH, in accordance with 42 CFR part 84: (1) issues certificates of approval for respirators which have met specified construction, performance, and protection requirements; (2) establishes procedures and requirements to be met in filing applications for approval; (3) specifies minimum requirements and methods to be employed by NIOSH and by applicants in conducting inspections, examinations, and tests to determine effectiveness of respirators; (4) establishes a schedule of fees to be charged for testing and certification; and (5) establishes approval labeling requirements. Information is collected from those who request services under 42 CFR part 84 in order to properly establish the scope and intent of request.

Information collected from requests for respirator approval functions includes contact information and information about factors likely to affect respirator performance and use. Such

information includes, but is not necessarily limited to, respirator design, manufacturing methods and materials, quality assurance plans and procedures, and user instruction and draft labels, as specified in the regulation.

The main instrument for data collection for respirator approval functions is the Standard Application Form for the Approval of Respirators (SAF), currently Version 9. Respirator manufacturers are the respondents (estimated to average 140 each year) and upon completion of the SAF, their requests for approval are evaluated. A total of 375 applications were submitted in CY2019, which preceded the surge in application received in conjunction with the COVID–19 pandemic. The applications are submitted, at will, and taking into account both historical conditions as well as the current situation, our prediction of the number of respondents each year for the next three years is 140. A $200 fee is required for each application. Respondents requesting respirator approval or certain extensions of approval are required to submit additional fees for necessary testing and evaluation as specified in 42 CFR parts 84.20–22, 84.66, 84.258 and 84.1102. Applicants are required to provide test data that shows that the manufacturer is able to ensure that the respirator is capable of meeting the specified requirements in 42 CFR part 84. The requirement for submitted test data is likely to be satisfied by standard testing performed by the manufacturer and is not required to follow the relevant NIOSH Standard Test Procedures. As additional testing is not required, providing proof that an adequate test has been performed is limited to providing existing paperwork.

The secondary instruments for data collection for respirator approval functions are instruments used to collect data from human participants who are serving as test fixture surrogates to perform tests while wearing the respirator being evaluated. Such instruments are completed by the human participant or test operator and are limited to specific information required for the test.

Approvals under 42 CFR part 84 offer corroboration that approved respirators are produced to certain quality standards. Although 42 CFR part 84 Subpart E prescribes certain quality standards, it is not expected that requiring approved quality standards will impose an additional cost burden over similarly effective quality standards that are not approved under 42 CFR part 84. Manufacturers with current approvals are subject to site audits by the Institute or its agents. Audits may occur periodically (typically every second year), or because of a reported issue. Approximately, 50% of the sites are audited each year, each having a primary point of contact. It is estimated that the average number of site audits over the next three years will be 85.

CDC requests OMB approval for an additional three years of data collection. The estimated annual burden hours are 131,059.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Business or other for-profit	Standard application form	140	4	229
	Request manufacturing code	10	1	30/60
	Site audits, Part 1	85	1	30/60
	Site audits, Part 2	85	1	9/60
	Site audits (completed for each corrective action)	70	2	16
Member of general public	Information sheet (initial participant visit only—contact info)	10	1	9/60
	Informed consent (annually, all test participants)	40	1	15/60
	Health and wellness screening (annually, all test participants)	40	1	15/60
	Health and wellness screening (each test, fit testing)	40	20	6/60
	Health and wellness screening (each test, man testing)	10	10	15/60
	Data collection form (man testing)	10	10	45/60
	Capacity test	10	1	6/60
	Communication Tests	10	1	2
	Donning test	10	1	1
	Fit test STP 5_5.1_6	14	20	9/60
	Fit tests STP–9 and 10	14	20	9/60
	Fogging test	10	1	30/60
	LRPL_Bitrex_Donning	38	1	1
	Performance Test	10	1	1
	Sound level STP–30_STP–111	25	2	6/60
	Stressors	10	1	1
	Test 118	10	25	30/60
	Test 147	10	4	9/60
	Wearability test	10	1	18/60

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